Message

From: Orme-Zavaleta, Jennifer [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C5A111DC377411595E5B24B5D96146B-ORME-ZAVALETA, JENNIFER]
Sent: 4/7/2021 3:16:49 PM
To: D'Amico, Louis [DAmico.Louis@epa.gov]
CC: Hubbard, Carolyn [Hubbard.Carolyn@epa.gov]
Subject: RE: FYI

Yep, dealing w it

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C Ex. 6 Personal Privacy (PP)

From: D'Amico, Louis <DAmico.Louis@epa.gov>
Sent: Wednesday, April 7, 2021 11:13 AM
To: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
Cc: Hubbard, Carolyn <Hubbard.Carolyn@epa.gov>
Subject: FYI

Not sure if this will be causing a dust up or not Ex. 5 Deliberative Process (DP) ?

https://insideepa.com/tsca-news/epa-scientist-sees-pfas-class-sticky-question-not-defensible

April 7, 2021

EPA Scientist Sees PFAS Class As 'Sticky Question,' Not 'Defensible'
April 6, 2021
EPA researcher Justin Conley told North Carolina officials at a recent hearing that the complex nature of per- and polyfluoroalkyl substances (PFAS) makes the decision of whether to group them in a single class for regulation "a sticky question," arguing that the broad restrictions are "likely a more protective approach" but not "necessarily defensible."

But Conley says it may be possible to group some PFAS into smaller sub-classes.

His comments appear likely to raise the bar for environmentalists and others who have long been urging regulators to group PFAS for assessment and regulatory purposes in an effort to speed scrutiny of the thousands of chemicals in the class, though given the difficulty of a single-class approach, environmentalists have also suggested a smaller sub-group approach.

Industry groups generally oppose a single class approach but industry groups, including the American Chemistry Council (ACC), have recently acknowledged the possibility of a sub-class approach.

"Although the grouping of some substances within the class based on similar physical, chemical, and biological properties may be possible -- a proposal to regulate all PFAS as a single class is neither scientifically accurate nor appropriate," ACC said in a document released in February.

North Carolina is one of several states investigating whether or how to group PFAS for assessment and regulatory purposes, and its science advisory board (SAB) used the March 5 meeting to hear perspectives on that method from stakeholders including EPA scientists, regulators from other states, and industry representatives.

Conley, a scientist at EPA's Office of Research and Development, was among the featured speakers at a March 5 public meeting hosted by the North Carolina's Secretaries' Science Advisory Board (SAB).

While Conley was slated to speak on his own research on PFAS found in North Carolina, including findings that exposures to the perfluorinated chemicals GenX, PFMOAA and NBP2 raised risks of neonatal mortality in rats, the panel's questions focused on the high-profile policy question of whether to regulate the chemicals as either a single class or in "subgroups" rather than individually.

For example, PFAS researcher Jamie DeWitt, an associate professor of pharmacology and toxicology at East Carolina University and advisory board member, who has worked on a series of recent papers offering policymakers different approaches for grouping PFAS, asked Conley whether he had "any specific scientific opinions that you can share on grouped approaches."

Conley said that he thought the answer was scientifically complex, as "sulfonates and carboxylates" have different developmental toxicology pathways, and may not impact the same tissues in the human body, though they both "involve alteration of lipid and glucose metabolism and transfer."

"From the outermost chemical effect perspective, at least the two chemicals we've studied so far all produce a common effect of neonatal mortality," Conley said. "So I would argue one protective approach would be to group all of them based on a shared adverse effect like that, as opposed to narrowly grouping specifically based on molecular initiating event."

Integrated Addition Model

EPA is also weighing how PFAS might be grouped through an ongoing non-animal toxicity testing project, though one official has said that while the testing is proving difficult, EPA expects to eventually produce results that could be used to prioritize further testing.

One option, Conley suggested, would be "an integrated addition model where we are subgrouping carboyxlates and sulfonates but then bringing the responses of those subgroups together in an integrated model approach."

"Some papers show integrated addition as a way to kind of subgroup chemicals based on molecular mechanism mode of action but then share similar downstream adverse outcomes," he said. "And I think that is likely a more protective approach. But it's a sticky question in terms of, do you just want all of them together all at once? I'm not sure if that's necessarily defensible either."

C. Mark Smith, director of the Massachusetts Department of Environmental Protection (MassDEP)'s Office of Research and Standards and Sandra Baird, a toxicologist with MassDEP, later presented on the scientific basis for the strict subgrouping approach that their state has taken on PFAS.

But American Chemistry Council senior director Steve Risotto weighed in in response, saying, "As touched on in his discussion, the concept of grouping or subgrouping of PFAS is a significant challenge with many unanswered questions remaining. In fact, it's possible we have yet to identify the right questions to ask."

Risotto continued by calling the MassDEP approach to subgrouping into question, saying, "While we are very supportive of this research at EPA, ACC is very concerned about arbitrary approaches to grouping PFAS, such as the drinking water standards in Massachusetts that you have just heard about."

ACC has previously pushed back against Massachusetts' move to group six PFAS together under a single drinking water standard, saying in 2020, "The grouping of substances under a single standard is justified only when the substances are believed to cause adverse health effects by the same mechanism of action. This is clearly not the case for the six substances identified by MassDEP."

Risotto echoed these same concerns, saying, "For example, among the 6 PFAS included in the Massachusetts regulation are two substances for which very little information is available. For one of those substances, HPFHPA, MASSDEP itself acknowledged that available data are not sufficient to consider it as being toxicologically equivalent to the other PFAS. The other substance, PFDA, was a last-minute addition to the regulation, for which MASSDEP conducted little, if any analysis to support its conclusion."

Dewitt responded to Risotto directly, saying that she had read "with interest" the ACC's recent document on grouping approaches for PFAS, and that she wondered what Risotto's thoughts were on recent papers that showed scientific support for the method, including a 2020 paper she had worked on with Ian Cousins.

"We at ACC are very supportive of the grouping approach, or a sub-grouping approach -- finding ways to address substances other than individually," Risotto said. "I don't agree that there's enough data to support a scientifically supportable rational approach to subgrouping. We just don't know that there is data available for that many substances, or for a real underlying approach to what is the endpoint that we should be using as the basis for the grouping."

"I don't want to go down the path of a back-and-forth," Dewitt replied, "but I just wanted to point out that some of the grouping approaches have suggested that the concept of persistence is sufficient because a vast majority of PFAS are persistent or degrade to persistent PFAS end products."

Risotto responded by saying that he thinks it is "not clear that persistence itself," is a valid reason for grouping PFAS, and that he "would not support regulating those based purely on persistence." -- Diana DiGangi (ddigangi@iwpnews.com)

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